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(54) Graft for intraluminal delivery into a body passageway.

(57) A graft for intraluminal delivery into a body passageway such as an aorta is described. The graft comprises an elongate tube (160) formed of a plurality of expandable and deformable first tubular members (201) aligned with their longitudinal axes parallel to each other. Each tubular member (201) may be detached and spaced apart from adjacent tubular members. Alternatively, adjacent tubular members (201) may be connected by a flexible connector member disposed between the tubular members. The plurality of tubular members (201) is embedded within a layer (202) of a deformable and expandable plastic material. The graft also comprises means for securing an end of the tube (160) within the body passageway, the securing means being a second expandable and deformable tubular member (166) connected to the end of the tube (160). The second tubular member (166) is expandable from a first to a second diameter upon the application, from the interior, of a radially outwardly extending force. The first diameter permits intraluminal delivery of the graft into the body passageway. The second diameter, which is variable and dependent upon the amount of force applied, enables the graft to be secured within the body passageway.

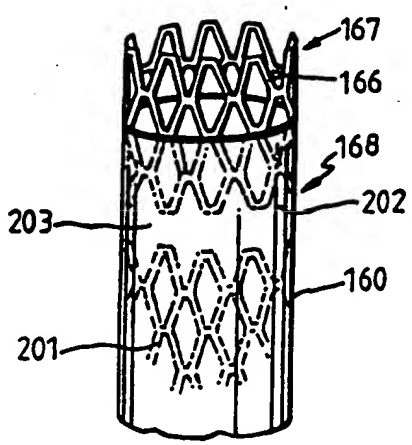

Fig. 10B

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conventional surgery on an expedited basis because of the extent of the surgery.

It has been previously proposed to repair abdominal aortic aneurysms by intraluminal delivery of an aortic graft disposed upon a catheter, and securing the graft within the aorta by expansion and deformation of an expandable deformable member associated with the graft by expanding and inflating a portion of the catheter which contacts the tubular member. Because of the relatively large diameter of the catheter and associated graft necessary for implantation within the aorta, some difficulties have been sometimes encountered, such as spasms associated with the access body vessel such as the femoral artery. Additional problems sometimes encountered with this method or repairing an abdominal aortic aneurysm have been kinking and/or twisting of the flexible, collapsible graft during and/or after implantation of the graft.

Accordingly, prior to the development of the present invention, there has been no bilateral intra-aortic bypass graft for intraluminal delivery, or method and apparatus for repairing an abdominal aortic aneurysm, which: does not have a relatively high morbidity and mortality rate; does not have an extended recovery period; does not require suturing the graft to the remaining aorta wall; permits the existing thrombosis therein to support and reinforce the graft; is suitable for older patients with chronic illnesses; is less susceptible to kinking and/or twisting of the graft; and is able to use a smaller diameter delivery system. Therefore, the art has sought a bilateral intra-aortic bypass graft for intraluminal delivery, and method and apparatus for repairing an abdominal aortic aneurysm which is believed to: not have a high morbidity and mortality rate; does not require an abdominal incision and general anesthesia; not require an extended recovery period; not require suturing the graft to the remaining aortic wall; permit the existing aortic wall and thrombosis therein to be retained to reinforce and support the aortic graft; be suitable for patients having other chronic illnesses; be less susceptible to kinking and/or twisting of the graft and permit the use of a smaller diameter delivery system.

SUMMARY OF THE INVENTION

In accordance with the invention, the foregoing advantages have been achieved through the graft of the present invention.

According to the present invention, a graft for intraluminal delivery into a body passageway comprises an elongate tube having first and second ends and formed of a plurality of expandable and deformable first tubular members, each tubular member having a longitudinal axis, the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other, each tubular member being detached and spaced apart from adjacent tubular members, and the plurality of tubular members being embedded within a layer of a deformable and expandable plastic material; and means for securing the first end of the tube within a body passageway, the securing means comprising a second expandable and deformable tubular member having first and second ends, the first end of the tube being connected to the second end of the second tubular member, the second tubular member having a first diameter which permits intraluminal delivery of the tubular member and tube into the body passageway and the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, the second diameter being variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to secure the first end of the tubular member within the body passageway.

The method for repairing an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith, enabled by the present invention, may include the steps of: disposing a first graft, having a first tube connected to a first, expandable and deformable, tubular member, upon a first catheter, disposing a second graft, having a second tube connected to a second, expandable and deformable, tubular member, upon a second catheter, each catheter having an expandable, inflatable portion with the tubular members disposed upon the expandable, inflatable portions and at least one of the grafts being in accordance with the present invention; intraluminally delivering the first and second grafts and catheters to the aorta and disposing at least a portion of each tube within the abdominal aortic aneurysm; and expanding the expandable, inflatable portion of each catheter to expand and deform the tubular members to force the tubular members radially outwardly into contact with the aorta and each other, to secure the tubular members and at least a portion of each tube within the aorta, whereby the tubes provide a bilateral fluid passageway through the abdominal aortic aneurysm.

Another feature of the method enabled by the present invention may include the step of simultaneously expanding the expandable, inflatable portions of each catheter. An additional feature of the present invention is that the respective tubes of the first and second grafts may each have first and second ends, the first end of each tube being connected to a tubular member and being disposed within the aorta; and the second end of the

Another feature of the bilateral bypass graft employing the graft of the present invention is that at least a portion of the first and second tubes are in an abutting relationship with each other when the first and second tubular members have their second, expanded and deformed diameter. An additional feature of the present invention is that a third expandable and deformable tubular member may be connected to the second end of the first tube; a fourth expandable and deformable tubular member may be connected to the second end of the second tube; and the third and fourth tubular members may be expanded and deformed to force the third and fourth tubular members radially outwardly into contact with an iliac artery by the expansion of the expandable, inflatable portion of each catheter associated with each tube.

A further feature of the present invention is that each tube may be formed of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other, each tubular member being detached, and spaced apart, from adjacent tubular members; and the plurality of tubular members may be embedded with a layer of a deformable and expandable plastic material. The plastic material may be silicone, polytetrafluoroethylene, expanded polytetrafluoroethylene, or expanded polyurethane.

Another feature of the present invention is that the first and second tubular members may be connected to the first and second tubes by embedding a portion of the second ends of the first and second tubular members in the deformable and expandable plastic of the tube to which it is to be connected.

An additional feature of the present invention is that each tube, or at least one of the tubes, may be formed of a plurality of expandable, and deformable tubular members, each tubular member having a longitudinal axis with a plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other; each tubular member being spaced apart from adjacent tubular members with a single, flexible connector member being disposed between adjacent tubular members; and the plurality of tubular members may be embedded within a layer of a deformable and expandable material. A further feature of the present invention is that the first and second tubular members may be connected to the first and second tubes by embedding a portion of the second ends of the first and second tubular members in the deformable and expandable plastic material of the tube to which it is to be connected.

In accordance with the present invention, the foregoing advantages have also been achieved through employing the graft of the present invention in an apparatus for repairing an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith. Such an apparatus includes: first and second grafts including first and second tubes respectively, each tube having first and second ends and a wall surface disposed between the two ends; first and second expandable and deformable tubular members, each expandable and deformable tubular member having first and second ends and a smooth outer wall surface disposed between the first and second ends, the first end of a tube being secured to a second end of a tubular member, the expansion and deformation of the tubular members being controllable; and two catheters, each catheter having an expandable, inflatable portion associated therewith, the tubular members being releasably mounted upon the inflatable portion of each catheter, whereby upon inflation of the expandable, inflatable portion of each catheter, the tubular members are forced radially and outwardly into contact with the aorta and each other to remain secured thereto, whereby the tubes, secured to the tubular members, provide a bilateral passageway through the abdominal aortic aneurysm; at least one of the grafts being in accordance with the present invention.

A further feature of the apparatus employing the graft of the present invention is that each tube may be formed of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other, each tubular member being detached, and spaced apart, from adjacent tubular members; and the plurality of tubular members may be embedded within a layer of a deformable and expandable plastic material. An additional feature of the present invention is that the expandable, inflatable portion of each catheter may extend along a portion of the length of each catheter a distance greater than the combined length of each tube and tubular member, whereby upon expansion and inflation of each expandable, inflatable portion of each catheter, each tubular member and its connected tube are simultaneously expanded.

The bilateral intra-aortic bypass graft for intraluminal delivery, and method and apparatus for repairing an abdominal aortic aneurysm enabled by the present invention, when compared to previously proposed prior art grafts and methods and apparatus for repairing aneurysms, are believed to have the advantages of: a lower mortality rate; shortened recovery periods; not requiring suturing a graft to the aorta; utilizing the existing aortic wall and thrombosis therein to support and reinforce the aortic graft; being suitable for use with patients

greater detail, the tubular members 166A, 166B, have a second, expanded and deformed diameter D' (FIGS. 5 and 11), the second diameter D' being variable and dependent upon the amount of force applied to the tubular members 166A, 166B, whereby the tubular members 166A, 166B, may be expanded and deformed to secure the first ends 167A, 167B of the tubular members 166A, 166B to the aorta 152, and a bilateral passageway 200 (is formed within the abdominal aortic aneurysm 151) by passageways 191A, 191B extending through the tubular members 166 and tubes 160. Preferably, as seen in FIGS. 5 and 11, at least a portion of the first and second tubes 160A, 160B is in an abutting relationship, the abutting portions of the first and second tubes 160A, 160B, being generally disposed toward the upper ends 161A, 161B of tubes 160A, 160B, whereby bilateral intra-aortic bypass graft 150, after implantation within aorta 152 and aneurysm 151, generally has an inverted Y-shaped configuration, as illustrated in FIGS. 5 and 11. Additionally, after tubular members 166A, 166B have been expanded and have their second, expanded and deformed diameter D', at least a portion, and preferably all of, the first and second tubular members 166A, 166B, are in an abutting relationship, as seen in FIGS. 5 and 11.

With reference to FIG. 1, each tubular member 166A, 166B preferably has a smooth outer wall surface 169A, 169B disposed between its first and second ends 167A, 167B, 168A, 168B. Wall surfaces 169A, 169B, preferably have a substantially uniform thickness with a plurality of slots 173 formed therein, the slots 173 being disposed substantially parallel to the longitudinal axes of the tubular members 166A, 166B. It has been found that one type of tubular member 166, which is particularly useful as securing means 165 are the expandable intraluminal grafts disclosed in U.S. Patent No. 4,733,665, issued March 29, 1988; U.S. Patent No. 4,739,762, issued April 26, 1988; and U.S. Patent No. 4,776,337, issued October 11, 1988, all of the foregoing patents being in the name of Julio C. Palmaz, and assigned to Expandable Grafts Partnership. Each of these patents is incorporated herein by reference. Other tubular members 166 could be utilized as securing means 165, provided they have the ability to be controllably expanded and deformed from the first diameter D, which permits intraluminal delivery of securing means 165, to the second expanded and deformed diameter D', in order to secure the tubular members 166A, 166B, and their connected tubes 160A, 160B within aorta 152.

Before describing the construction of an embodiment of the present invention, for comparison purposes an alternative graft construction described and claimed in our European Patent Application No. 0551179 will now be described with reference to FIGS. 1 and 11.

With reference to FIGS. 1 and 11, tubes 160A, 160B preferably have a generally, circular cross-sectional configuration, and tubes 160A, 160B may be made from a variety of materials, provided they have the requisite strength characteristics to be utilized as a bypass graft 150, as well as have the requisite compatibility with the human body in order to be used as a graft, or implant material, without being rejected by the patient's body. Examples for such materials are DACRON ® and other polyester materials, TEFLON® (polytetrafluoroethylene), TEFLON® coated DACRON®, porous polyurethane, silicone, expanded polytetrafluoroethylene, and expanded polyurethane. It is preferred that all of the foregoing materials be porous to allow for an intimal layer to form on the tubes 160. Additionally, tubes 160A, 160B can be made by the replamineform replicated life forms process, which is a method for fabricating uniformly microporous materials from marine skeletal structures. The foregoing described fabric materials can be knitted or woven, and can be warp or weft knitted. If the material is warp knitted, it may be provided with a velour, or towel like surface, which speeds up clotting of blood which contacts tubes 160A, 160B in order to increase the attachment, or integration, of tubes 160A, 160B to aorta 152, or to assist the integration of tubes 160A, 160B to the thrombosis 154. Tubes 160A, 160B can also be made of a bio-erodible, or degradable material, such as albumin or collagen or a collagen coated material. A tube 160 which is bioerodible, would erode and dissolve, or degrade, over a period of time; however, it is believed that a layer of endothelium, or skin, will grow as the tubes 160A, 160B erode, the new layers of endothelium, or skin, provide a new, fluid impervious lining within aneurysm 151. In some procedures, it might be desirable to make tubes 160A, 160B of a fluid impervious material. Additionally, tubes 160A, 160B, as well securing means 165, or tubular members 166A, 166B, could have a coating of a biologically inert material, such as TEFLON® or porous polyurethane.

If any of the foregoing described materials are used for the manufacture of tubes 160A, 160B, the first ends 161A, 161B of tubes 160A, 160B may be connected to the second ends 168A, 168B of the tubular members 166A, 166B, as by a plurality of conventional sutures of polypropylene, DACRON®, or any other suitable material. Preferably, the ends 161A, 161B of tubes 160A, 160B overlap and cover the second ends 168A, 168B of tubular members 166A, 166B, such overlapping being approximately 50% of the length of tubular member 166A, 166B. The first ends 161A, 161B of tubes 160A, 160B,

With reference to FIG. 15, another embodiment of bilateral intra-aortic bypass graft 150 is illustrated. Graft 51' includes means for securing 192 the lower ends 162A, 162B of tubes 160A, 160B to the two iliac arteries 153. Securing means 192 preferably includes a third expandable and deformable tubular member 166A' connected to the second end 162 of the first tube 160A, and a fourth expandable and deformable, tubular member 166B' connected to the second end 162B of the second tube 160A. Preferably, third and fourth members 166A', 166B' are of the same type of construction as those used for securing means 165, or tubular members 166A, 166B. Third and fourth tubular members 166A', 166B' may be connected to the lower ends 162A, 162B of tubes 160A, 160B, as by means of sutures, previously described, when tubes 160A, 160B are of fabric, or similar construction, as previously described. Alternatively, if tubes 160A, 160B, have the construction as illustrated in FIGS. 9, 10A, and 10B, third and fourth tubular members 166A', 166B' may be also connected as by conventional sutures, as previously described, or preferably may be secured to the lower ends 162A, 162B of tubes 160A, 160B, by embedding a portion of the first ends 167A, 167B of tubular members 166A', 166B' in the deformable and expandable plastic material 202 disposed at the second ends 162A, 162B of tubes 160A, 160B as previously described in connection with FIG. 10B. As will be hereinafter described in further detail, securing means 192, or third or fourth tubular members 166A', 166B', may be expanded and deformed in the same manner as securing means 165 to force the third and fourth tubular members 166A', 166B' into contact with an iliac artery, 153L, 153R. Although the flow of pumped blood downwardly through aorta 152 and into iliac arteries 153L, 153R is believed to provide enough pressure to maintain bilateral passageways 191A, 191B, formed by tubes 160A, 160B, in their desired positions within iliac arteries 153L, 153R, as illustrated in FIGS. 11 and 15, there is a slight negative vacuum pressure component associated with the pumping pressure, whereby the securing means 192 might be required. Securing means 192 also serves to ensure no movement of passageways 191A, 191B, caused by a person's body movements.

With reference to FIGS. 1, 2, and 5, the method and apparatus for repairing an abdominal aortic aneurysm of the present invention will be described. Apparatus 180 for repairing an abdominal aortic aneurysm 151 generally comprises: first and second tubes 160A, 160B and first and second expandable and deformable tubular members 166A, 166B, tubular members 166 and tubes 160 being constructed as previously described; and two catheters 181A, 181B, each catheter have an expandable, inflatable portion 182A, 182B, or balloon 183 associated therewith and a nosepiece 184. The tubular members 166A, 166B are releasably mounted to the inflatable portion 182 of each catheter 181, in any suitable fashion, whereby upon inflation of the expandable, inflatable portion 182 of each catheter 181A, 181B, the tubular members 166A, 166B are forced radially outwardly into contact with the aorta 152 and with each other to remain secured to aorta 152, whereby the tubes 160A, 160B, secured to the tubular members 166A, 166B, provide a bilateral passageway 200, or bilateral passageways 191A, 191B (FIGS. 11 and 15) through the abdominal aortic aneurysm 151.

The apparatus 180 for repairing the abdominal aortic aneurysm 151 as illustrated in FIGS. 1 and 2, is in its configuration it would have for intraluminal delivery into aorta 152 and aneurysm 151. Preferably, the first tube 160A, tubular member 166A, and catheter 181A are intraluminally delivered through a first femoral artery; and the second tube 160B, tubular member 166B, and catheter 181B are intraluminally delivered through a second femoral artery and in turn each pass through an iliac artery 153L, 153R, as illustrated in FIG. 2. In the configuration shown in FIGS. 1 and 2, the tubular members 166A, 166B have their first unexpanded, undeformed diameter D. In FIG. 5, tubular members 166A, 166B, have been expanded and deformed into their second, expanded and deformed diameter D'. Expansion and deformation of tubular members 166A, 166B is controlled by the expansion of balloons 183 of catheters 181A, 181B in a conventional manner. When apparatus 180 is being intraluminally delivered, catheters 181A, 181B, tubular members 166A, 166B, and tubes 160A, 160B are preferably enclosed by conventional catheter sheathes 186A, 186B which are removed, as shown in FIG. 1, as apparatus 180 is disposed in its desired location within aorta 152.

If tubular members 166A, 166B, are utilized in connection with a fabric type tube 160, as previously described, balloon 183 of catheter 181 may have a length which extends from slightly beyond the first end 167 of tubular member 166, and to a position slightly beyond the second end 168 of tubular member 166. As illustrated in FIG. 5, if apparatus 180 includes tubes 160 constructed in a manner as described in FIGS. 9, 10A, and 10B, inflatable portion 182, or balloon 183 associated with each catheter 181 extends along a portion of the length of each catheter a distance greater than the combined length tube 160 and its associated tubular member 166, as illustrated in FIG. 5. Thus, upon expansion and inflation of each expandable and inflatable portion 182, or balloon 183, associated with each catheter 181, each tubular mem-

their longitudinal axes being substantially parallel with each other, each tubular member being detached and spaced apart from adjacent tubular members, and the plurality of tubular members being embedded within a layer of a deformable and expandable plastic material; and

means for securing the first end of the tube within a body passageway, the securing means being a second expandable and deformable tubular member having first and second ends, the first end of the tube being connected to the second end of the second tubular member, the second tubular member having a first diameter which permits intraluminal delivery of the tubular member and tube into the body passageway and the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, the second diameter being variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to secure the first end of the tubular member within the body passageway.

2. The graft of claim 1, wherein the securing means is adapted for securing the first end of the tube within an aorta as the body passageway.

3. The graft of claim 1 or 2, wherein the second tubular member is connected to the tube by embedding a portion of the second end of the second tubular member in the deformable and expandable plastic material of the tube to which it is connected.

4. The graft of any of the preceding claims, wherein the plastic material is silicone.

5. The graft of any claims 1 to 3, wherein the plastic material is polytetrafluoroethylene.

6. The graft of any of claims 1 to 3, wherein the plastic material is expanded polytetrafluoroethylene.

7. The graft of any of claims 1 to 3, wherein the plastic material is expanded polyurethane.

8. The graft of any of the preceding claims, wherein a single flexible connector member is disposed between adjacent tubular members of the plurality of first tubular members which form the tube.

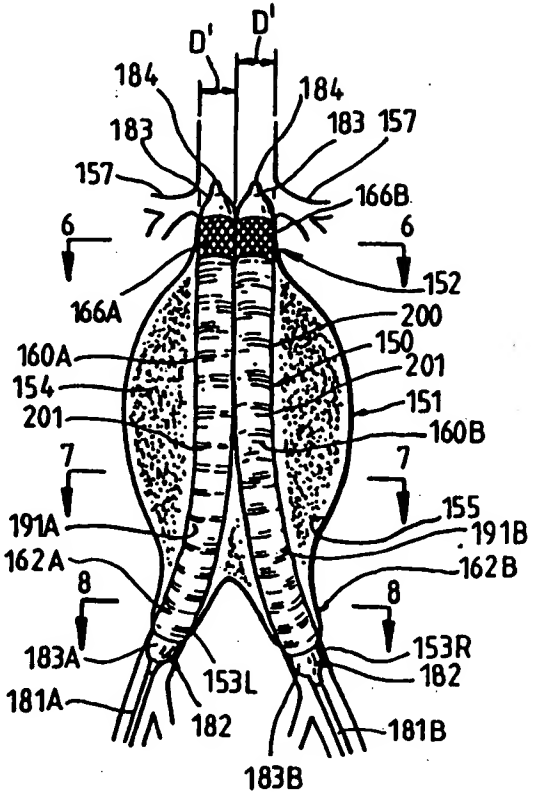


Fig. 5

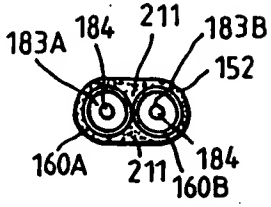
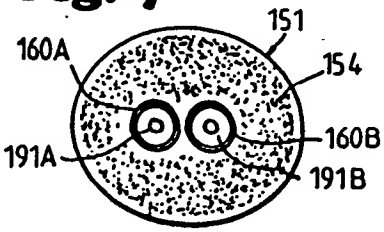


Fig. 6

Fig. 7



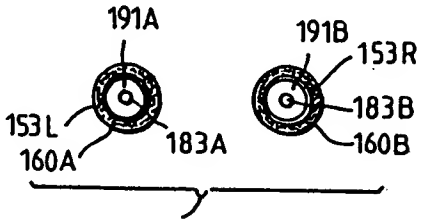


Fig. 8

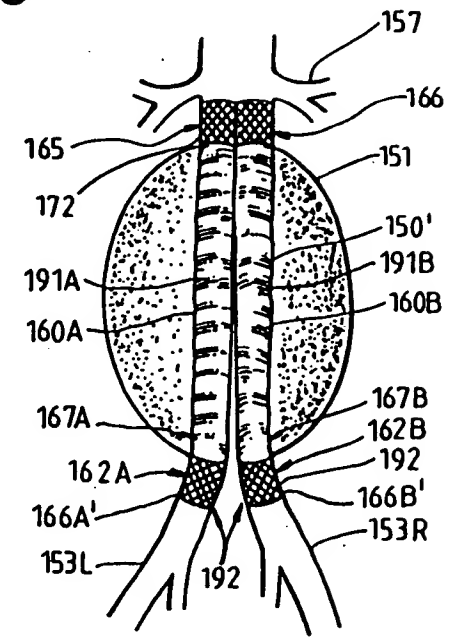


Fig. 15

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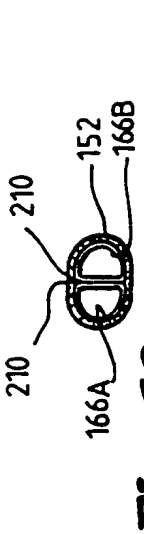

Fig. 12

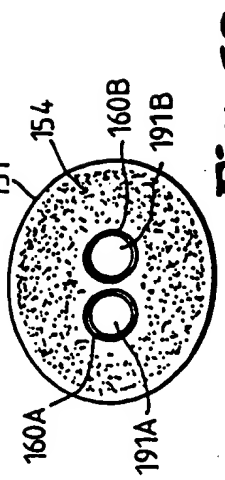

Fig. 13

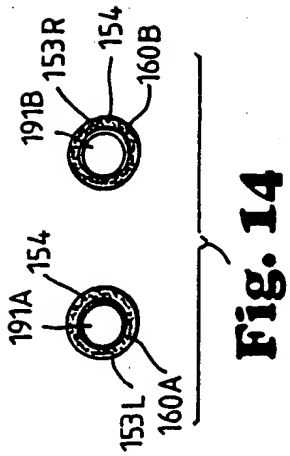

Fig. 14

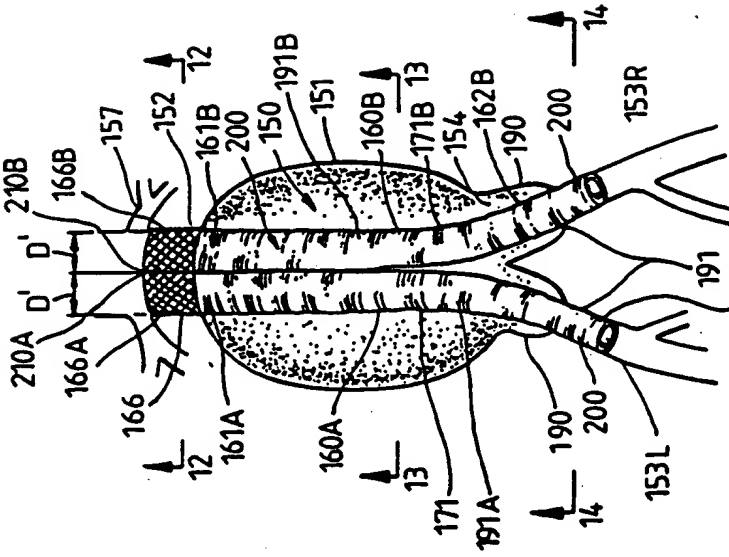

Fig. 11